(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 590 200 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **92116918.1**

(51) Int. Cl.[5]: **A61B 5/0205**

(22) Date of filing: **02.10.92**

(43) Date of publication of application:
06.04.94 Bulletin 94/14

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

(71) Applicant: **E.R. SQUIBB & SONS, INC.**
Lawrenceville-Princeton Road
Princeton New Jersey 08543-4000(US)

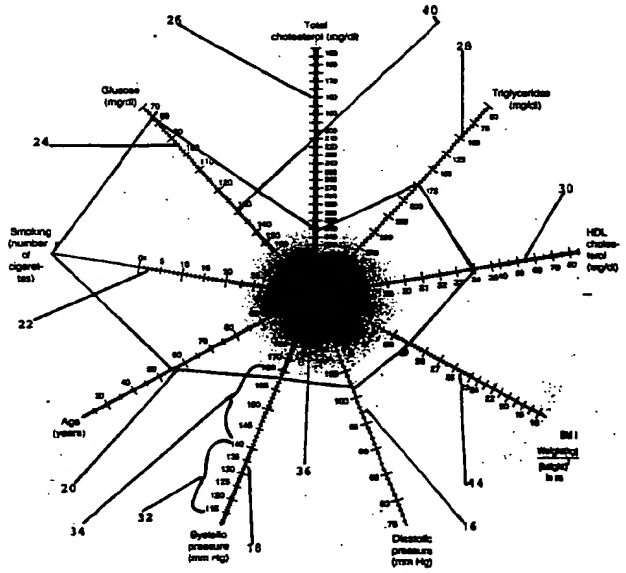
(72) Inventor: **Cuypers, Dirk, Dr. c/o Bristol-Myers Squibb**
Belgium
Terhulpsesteenweg 185
B-1170 Brussels(BE)

(74) Representative: **VOSSIUS & PARTNER**
Postfach 86 07 67
D-81634 München (DE)

(54) Device and method for the visualisation of cardiovascular risk factors.

(57) A device or system is provided for calculating and visualising the risk for developing coronary heart disease which is in the form of a cardiovascular risk diagram which includes a series of cardiovascular risk scales projected on cardiovascular risk areas (for example, delineated by different colours) each scale representing a different cardiovascular risk factor. Data for each cardiovascular risk are recorded on its appropriate risk scale, data points on adjacent risk scales are connected to form enclosed area superimposed over the risk areas. The resulting enclosed area is visually or otherwise compared to the total area of the circle, to determine a score of cardiovascular risk.

Fig. 2



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The present invention relates to a device and method for the visualisation of different cardivascular risk factors on a scale, projected in different risk areas, to give a cardiovascular risk diagram which can be used to predict coronary heart disease.

The major risk factors for coronary artery diseases are widely recognised. Age and gender have a powerful effect, but are immutable. Hypertension, cigarette smoking, total cholesterol and low density lipoprotein cholesterol double or more the risk.

Other important recognised risk factors are : overweight, left ventricular hypertrophy, glucose intolerance, hyperinsulinaemia and physical inactivity. (Brach, Cholesterol and coronary heart disease prevention. A transatlantic consensus. European Heart Journal, 1989, 10 : 702-711; Grundy, Cholesterol and coronary heart disease. Jama, Nov. 1986, Vol 256 : 2849-2858; The prospective cardiovascular Munster study : Prevalence and prognostic significance of hyperlipidemia in men with systemic hypertension. Am. J. Card., 1987, 59 : 9G-17G; Egan et al., Comparative effect of overweight on cardiovascular risk in younger versus older men. Am. J. Card., Feb. 1991, Vol. 67 : 248-252).

Further epidemiological studies have shown that for some cardiovascular diseases such as hypertension, assessment requires consideration of a multivariate risk profile. (W. Kannel et al., Office assessment of coronary candidates and risk factor insights from the Framingham study. J. of Hypertension, 1991, 9 (Suppl. 7) : S13-S19; K. Anderson et al., An updated coronary risk profile. Circulation, Vol. 83, n° 1, Jan. 1991 : 356-362; Prediction of coronary heart disease in Europe. The 2nd European Heart Journal (1991) 12 : 291-297).

Before starting any therapy for treating coronary artery disease, a complete assessment of overall cardiovascular risk factors is essential. Unfortunately, even where all such cardiovascular risk factors are recorded, there is no existing system for correlating these risk factors with probability of developing coronary heart disease.

The American Heart Association (AHA) (K. Anderson et al., supra) and the WHO-Erica project (Erica Research Group, supra) give different cardiac heart disease equations to predict the risk for developing coronary heart diseases. However, these mathematical formulas do not provide visualisation of the cardiovascular risks.

It is therefore apparent that there is a need for a device and method to visualise the most important risk factors for each patient for the benefit of the physician and the patient. The purpose of the present invention is to create a 'Cardiovascular Risk Manager (CVRM)'. Such a system could be used to evaluate the cardiovascular patient, to estimate his risk profile, to decide the therapeutic approach, and/or to increase the therapeutic compliance of the patient.

In accordance with the present invention, a device for the visualisation of the risk of coronary heart disease is provided, comprising a plurality of scales of different cardiovascular risk factors, each scale representing an individual risk factor.

In a further embodiment a cardiovascular risk device for delineating cardiovascular risk factors, which is used for predicting development of coronary heart disease in a patient, is provided, which is in the form of a diagram including a series of cardiovascular risk areas delineating low to high risk areas; a series of cardiovascular risk scales delineating low to high risk for various cardiovascular risk factors, superimposed over said cardiovascular risk areas, so that the cardiovascular risk factor delineated by each scale is correlated in degree of risk with the cardiovascular risk area over which it is superimposed. The numerical value of each of the cardiovascular risk factors of a patient represented on the cardiovascular risk scales, is marked on the appropriate cardiovascular scale as a data point, and the data points on adjacent cardiovascular risk scales are connected to form an enclosed area superimposed on said cardiovascular risk areas. The so-delineated enclosed area superimposed on the cardiovascular risk areas is compared to the total area.

In a preferred embodiment of the invention, the series of cardiovascular risk areas is formed of a series of concentric cardiovascular risk areas, which may be delineated by different shades and/or colours; and the series of cardiovascular risk scales is formed of an array of scales radially extending outwardly from a central point of the series of concentric cardiovascular risk areas. Each of the cardiovascular risk scales represents a different cardiovascular risk factor. The cardiovascular risk scales are preferably formed of radially extending axes or spokes projected over the concentric cardiovascular risk areas, converging at the central point of the concentric cardiovascular risk areas.

In the preferred embodiment of the invention, the most external concentric cardiovascular risk area represents the normal risk area, so that projected data on the cardiovascular risk scales which fall on the normal risk area are to be considered as normal values; the innermost concentric cardiovascular risk area is the highest risk area, so that projected data on the cardiovascular risk scales which fall in the highest risk area are considered as high risk values; and the concentric cardiovascular risk area(s) between the normal

risk or outermost area and the highest risk or innermost area, are elevated risk areas. Each of the cardiovascular risk areas are preferably delineated by different colours and/or shades or by other visual means such as cross-hatching, pin-points and the like.

It will be appreciated that the cardiovascular rish areas may, in addition to being a plurality concentrically dispesed areas, take the form of a series of other shaped areas superimposed on each other such as rectangular areas square areas and the like.

It is preferred that the cardiovascular risk scales extend across such risk areas starting from a common central point disposed within the smallest risk area.

The cardiovascular risk factors represented by the cardiovascular risk scales include one or more of age, weight, blood pressure (systolic and diastolic), lipid parameters including total cholesterol, triglycerides, low and/or high density lipoproteins, glycemic parameters and/or smoking habits. For example, in a preferred embodiment of the invention, the cardiovascular risk factors represented by the cardiovascular risk scales include age (years), systolic pressure (mmHg), diastolic pressure (mmHg), weight (kg or lb), LDL-cholesterol or HDL-cholesterol (mg/dl), triglycerides (mg/dl), smoking (number of cigarettes per day).

In addition, in accordance with the present invention there is provided a method for predicting coronary heart disease employing the cardiovascular risk device as defined above.

Furthermore, a method for the visualisation of the risk of coronary heart disease is provided, comprising measuring different cardiovascular risk factors and displaying said risk factors on different risk factor scales. In a further embodiment a method of the invention is designed for calculating and visualising the risk of developing coronary heart disease, and includes the steps of providing a diagram which includes a series of cardiovascular risk areas delineating low to high cardiovascular risk areas; and a series of cardiovascular risk scales for various cardiovascular risk factors, delineating low to high cardiovascular risk for each risk factor, superimposed over the cardiovascular risk areas; determining a numerical value for each cardiovascular risk factor of a patient, represented on the cardiovascular risk scales; recording such numerical value on the appropriate cardiovascular risk scale as a data point; connecting data points on adjacent cardiovascular risk scales to form an enclosed area superimposed on the cardiovascular risk areas, comparing the so-delineated enclosed area superimposed on the cardiovascular risk areas with the total area to determine a score of cardiovascular risk used to predict development of coronary heart disease.

The invention is described in detail in connection with the drawings in which:

Figure 1 is a graphic view of a cardiovascular risk diagram in accordance with the present invention; and

Figure 2 is a graphic view of a cardiovascular risk diagram in accordance with the invention which includes a polygonic graphic presentation of the cardiovascular risk factors of a patient.

Figure 3 is a graphic view of a cardiovascular risk diagram in accordance with the invention wherein the cardiovascular risk areas are delineated by green and orange colour shades.

Referring to the accompanying figures, wherein like numerals represent like components in the two views, the cardiovascular risk device 10, in accordance with the present invention, is an integrated diagram or system of a pictorial representation of a patient's cardiovascular risk profile on paper. As shown in Figure 1, the device 10 is formed of a series of cardiovascular risk scales or axes 14 to 30, for various cardiovascular risk factors 14a to 30a, superimposed over a series of cardiovascular risk areas 32, 34, 36 as designated by different shades and/or colours. Each axis, 14 to 30, corresponds to a cardiovascular risk parameter 14a to 30a, respectively. Physically, the axes are subdivided in three areas each corresponding to a cardiovascular risk area such as designated by the following: green outer area 32 (no risk); orange middle area 34 (moderate risk) or red inner area 36 (high risk).

The cardiovascular risk factors which may be expressed on the cardiovascular risk device of the invention include, but are not limited to, age, weight parameters, diastolic and systolic blood pressure, left ventricular hypertrophy, lipid parameters such as total cholesterol, triglycerides, high density lipoproteins and/or low density lipoproteins, glycemic parameters, smoking habits and the like. The above risk factors may be expressed as actual values logarithmically, or as a percentage of a reference value on the cardiovascular risk scales superimposed or projected on areas of the device which represent different risk areas, the number of which are a function of defined risk areas. The risk areas can be symbolically presented as concentric areas, polygonal areas such as square or rectangular areas, and the like. Preferably four to twelve parameters represented by scales are used. Particularly preferred are eight, nine or ten scales.

The combination of the cardiovascular risk factors on the cardiovascular scales or axes superimposed on the cardiovascular risk areas provides the cardiovascular risk device of the invention. The cardiovascular risk device of the invention may be presented by any audio-visual method, such as paper, computer screen and the like.

The value obtained for a specific risk factor of a patient can be registered on a cardiovascular risk scale. The units for each scale are a function of the value the physician will use.

The polygonal surface area 40 formed by connecting data points of the cardiovascular risk scales as shown in figure 2 represents a risk profile which may be compared against the total area of the circle such as the area of the circle at the outer or inner limits of outer risk area 32 to obtain a score.

It will be appreciated that the cardiovascular risk axes or scales may be calibrated so that the high risk area is the inner cardiovascular risk area (such as 32) and the low risk area is the outer cardiovascular risk area (such as 36). In such case, the smaller the polygonal area 40 of the patient which may syxmbolize the cross section of an artery, the greater risk of developing coronary heart disease.

The following example represents a preferred embodiment of the invention.

EXAMPLE

Referring to the accompanying figures 1 and 2, a male patient of 55 years has a systolic pressure of 158 mmHg and a diastolic pressure of 102 mmHg. His height is 1,70 m and weight 83,8 kg. His plasma total cholesterol is 340 mg/dl, HDL-cholesterol 34 mg/dl and triglycerides 175 mg/dl. His glycemic value is 76 mg/dl. The patient does not smoke. As seen in Figure 1, these values are projected on each of the individual scales of the cardiovascular risk device 10 of the invention, which scales are positioned in a radial way all converging to one central point.

The different axis are projected on different risk areas 32, 34, 36. The most external concentric area 32 is considered to be the normal one (outside green area). Thus, the projected result which falls in that area can be considered as normal values. The second area 34 (orange) is considered as an area with an elevated risk. All values projected in that area must be considered as abnormal. The third concentric circle 36 (red) is considered as a very high risk area.

The threshold values for each cardiovascular risk factor corresponding to the three cardiovascukar risk areas are given in the following table.

Table 1

The threshold on the axes of the cardiovascular risk device of the ionvention corresponding to the three cardiovascular risk areas.			
Parameter	Low risk Green area	Medium Risk Orange area	High Risk Red area
Glucose (mg/dl)	70-100	110-140	140-200
Smoking (cig/day)	0-0	1-20	20-50
Age (years)	20-50	50-80	80-110
Systolic BP (mmHg)	110-140	140-160	160-220
Diastolic BP (mmHg)	75-90	90-105	105-120
Body Mass Index	15-25	25-30	30-45
HDL-cholesterol (mg/dl)	85-35	35-30	30-5
Triglycerides (mg/dl)	50-150	150-250	250-450
Total cholesterol (mg/dl)	150-200	200-300	300-500

In the present example, it can be observed that only two cardiovascular risk factors are considered as normal in the patient, namely his glucose value and that he is a non-smoker. On the other hand, the patient in question has seven elevated risk factors. As seen in Figure 2, by connecting the different values, a polygonic graphic presentation 40 of the cardiovascular risk factors of the patient Is obtained. Calculation of

the area of enclosed surface 40 or the ratio of the area of enclosed surface 40 and the total area of the circle is an index of severity.

In the present example, the relative area (ratio of the actual enclosed area and the total area of the circle) is 0.32 (= CVRM-score).

The corresponding score for developing a coronary heart disease using the Framingham (5 years) and the WHO-Erica model are -1.74 and -3.76 respectively.

The cardiovascular risk device of the invention score was correlated with the Framingham and the WHO-Erica models. To evaluate the value of the cardiovascular risk device of the invention, as a cardiovascular predictor for developing coronary heart disease, 97 cardiovascular patients (57 hypertensive patients and 40 hyperlipidemic patients) were evaluated using the CVRM-score, Framingham-score and the WHO-Erica-score. The correlation found between the CVRM-score and the WHO-score was -0.53 ($p < 0.0001$), between the CVRM-score and the Framingham-score -0.74 ($p < 0.0001$) and between the WHO-score and Framingham-score 0.70 ($p < 0.0001$).

A physician may use the cardiovascular diagram as shown in Figure 2 in which different cardiovascular reference values are shown to help decide which treatment to start and to evaluate the efficacy of the treatment.

A copy of the same diagram can be used to give to the patient. Howover, the lay-out can be only a symbolic one, just to inform the patient that for a specific risk factor, he has a problem. This will motivate the patient to better control his cardiovascular risk factors and to see his progression in function of time and therapeutic intervention.

The cardiovascular risk device of the invention can also be used for clinical/epidemiologic purposes.

The device of the invention can be used as a record form for the follow-up of clinical studies to evaluate specific cardiovascular risk factors. Indeed, the device of the invention can be coded as such, that reading of the axes can be done manually or electronically.

The method of the invention can also be adapted to be performed with the help of a computer programm, wherein the different cardiovascular risk factors will be entered into the computer system and on that basis an individual cardiovascular risk diagram will be generated and the total risk factor will be calculated. This procedure has the advantage that the number and selection of the risk factors can easily be varied, depending on the needed therapy. For the purpose of comparison, however, only diagrams consisting of the same number, selection and geometrical arrangement of the scales representing the risk factors should be used.

The cardiovascular diagram can also be visualised by a display means such as LEDs which are so connected that the entered risk factgors automatically cause displaying of the cardiovascular risk diagram.

Claims

1. A device for the visualisation of the risk of coronary heart disease, said device comprising a plurality of scales, each scale representing a different cardiovascular risk factor.

2. The device according to claim 1 wherein the scales are superimposed over different cardiovascular risk areas, to provide a cardiovascular risk diagram.

3. A cardiovascular risk device for delineating cardiovascular risk factors, which is used for predicting development of coronary heart disease, comprising a diagram including a series of cardiovascular risk areas delineating low to high risk areas; and

   a series of cardiovascular risk scales delineating low to high risk for various cardiovascular risk factors, superimposed over said cardiovascular risk areas, so that the cardiovascular risk factor delineated by each scale is correlated in degree of risk with the cardiovascular risk area over which it is superimposed.

4. The device according to claim 3 whereby the numerical value of each of the cardiovascular risk factors of a patient represented on the cardiovascular risk scales is marked on the appropriate cardiovascular risk scale as a data point, and the date points on adjacent cardiovascular risk scales are connected to form an enclosed area superimposed on said cardiovascular risk areas, and the surface of the so delineated cardiovascular risk area is compared to the total circle area to determine a score to predict development of coronary heart desease.

5. The device as defined in any of claims 2 to 4 wherein the series of cardiovascular risk areas is formed of a series of concentric cardiovascular risk areas, which may optionally be delineated by different shades and/or colours or by other visual means.

6. The device as defined in any of claims 1 to 5 wherein the series of cardiovascular risk scales is formed of an array of scales radially extending outwardly from a central point of said series of concentric cardiovascular risk areas.

7. The device as defined in any of claims 3 to 6 wherein each of said cardiovascular risk scales represents a different cardiovascular risk factor.

8. The device as defined in any of claims 1 to 7 wherein the cardiovascular risk scales comprise radially extending axes or spokes projected over different concentric cardiovascular risk areas and converging at the central point of said concentric cardiovascular risk areas.

9. The device as defined in any of claims 2 to 8 wherein the most external concentric cardiovascular risk area is the normal risk area, so that data projected on the cardiovascular risk scales which falls in the normal risk area are to be consiered as normal values.

10. The device as defined in any of claims 2 to 9 wherein the innermost cardiovascular risk area is the highest risk area, so that data projected on the cardiovascular risk scales which falls in the highest risk area are considered as high risk values.

11. The device as defined in any of claims 2 to 10 wherein the cardiovascular risk areas between the normal risk or outermost area and the highest risk or innermost area are elevated risk areas.

12. The device as defined in any of claims 2 to 11 wherein each of the cardiovascular risk areas are delineated by different colours and/or shades.

13. The device as defined in any of claims 1 to 12 wherein the cardiovascular risk factors represented by said cardiovascular risk scales include one or more of age, weight, blood pressure (systoplic and diastolic), lipid parameters including total cholesterol, triglycerides, low and/or high density lipoproteins, glycemic parameters and/or smoking habits.

14. The device as defined in any of claims 1 to 13 wherein to cardiovascular risk factors represented by said cardiovascular risk scales include age (years), systolic pressure (mmHg), diastolic pressure (mmHg), weight (kg or lb), LDL-cholesterol or HDL-cholesterol (mg/dl), triglycerides (mg/dl), total cholesterol (mg/dl), glucose (mg/dl), smoking (number of cigarettes per day).

15. The device as defined in any of claims 1 to 14 wherein the scales are presented nominal, logarithmic or as a percentage of a reference value.

16. The device as defined in any of claims 1 to 15 wherein the scales are aranged so that the values of the different risk factors of a patient displayed on the scales and connected with the values displayed on the two adjacent scales provide an area symbolizing the total risk factor.

17. The device as defined in any of claims 2 to 16 wherein the cardiovascular risk area is formed of a series of ever increasing polygonal cardiovascular risk areas, with the smallest area being enveloped by or superimposed within the next larger area.

18. The device as defined in any of claims 2 to 17 wherein the polygonal cardiovascular risk areas are square or rectangular in shape.

19. The device as defined in any of claims 2 to 18 wherein the concentric cardiovascular risk areas are delineated by different shades and/or colours.

20. A method for predicting coronary heart disease employing the cardiovascular risk device as defined in any of claims 1 to 19.

21. A method for the visualisation of the risk of coronary heart disease, comprising measuring different cardiovascular risk factors and displaying said risk factors on different risk factor scales.

22. The method according to claim 21 wherein the scales are superimposed over different risk areas, to provide a cardiovascular risk diagram.

23. A method for calculating and visualising the risk for developiong coronary heart disease, which comprises providing a diagram which includes a series of cardiovascular risk areas delineating low to high risk areas, and a series of cardiovascular risk scales for various cardiovascular risk factors delineating low to high risk, superimposed over said cardiovascular risk areas;

determining a numerical value for each cardiovascular risk factor of a patient, represented on the cardiovascular risk scales, recording such numerical value on the appropriate cardiovascular risk scale as a data point;

connecting data points on adjacent cardiovascular risk scales to form an enclosed area superimposed on the cardiovascular risk areas, comparing the so-delineated enclosed area superimposed on the cardiovascular risk areas against the total circle area to determine a score of cardiovascular risk.

24. The method as defined in claim 22 or 23 wherein the series of cardiovascular risk areas is formed of a series of concentric cardiovascular risk areas, which may or may not be delineated by different shades or colours.

25. The method as defined in any of claims 21 to 24 wherein the cardiovascular risk factors determined include one or more of age, weight, blood pressure (systolic and diastolic), lipid parameters including total cholesterol, triglycerides, low and/or high density lipoproteins, glycemic parameters and/or smoking habits.

26. The method as defined in any of claims 23 to 25 wherein the enclosed area of the patient is compared against the enclosed area of the total circle.

27. The method as defined in any of claims 23 to 26 wherein the enclosed area of the patient is compared against the total area of all cardiovascular risk areas.

Fig. 1

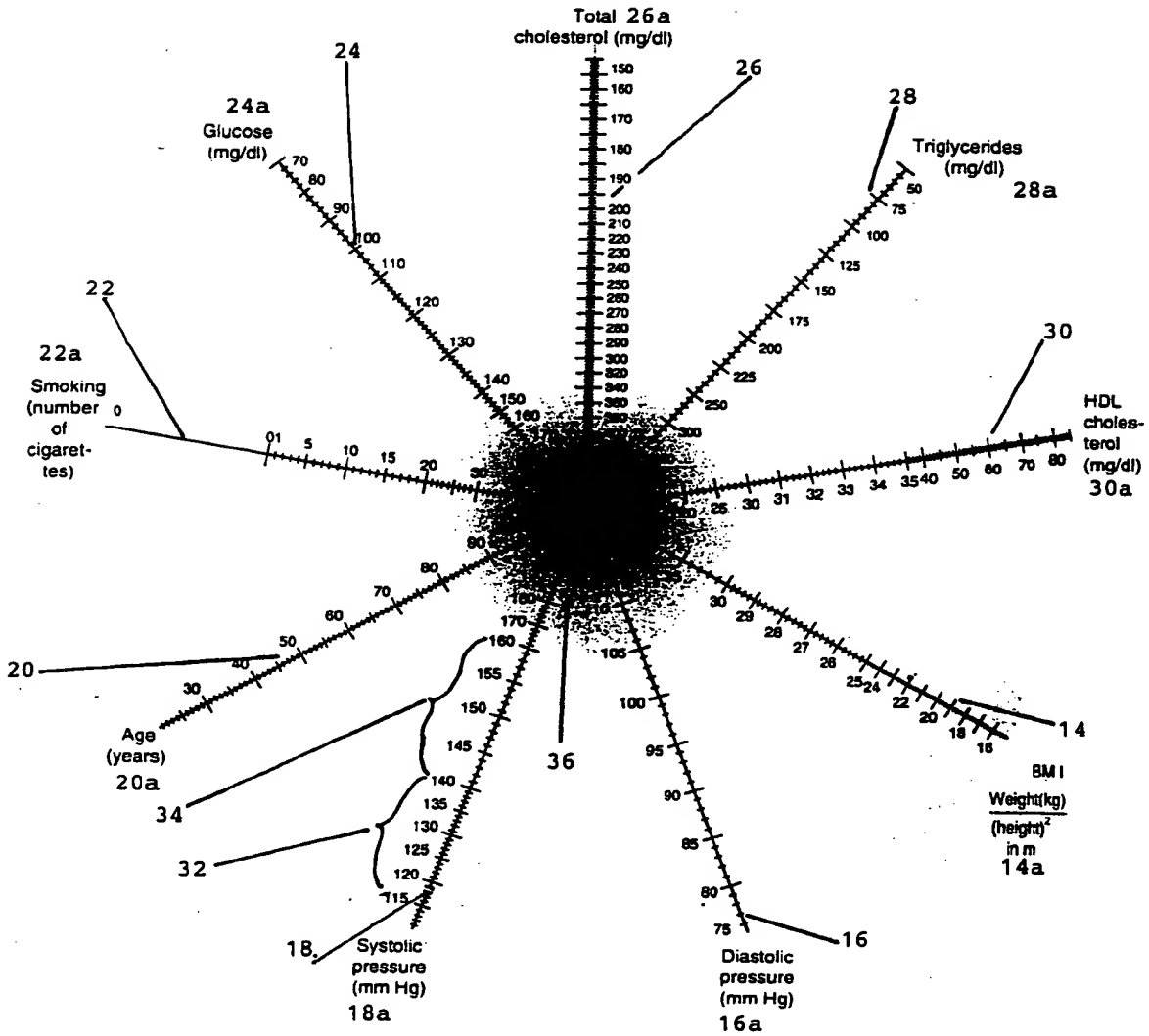

Total cholesterol (mg/dl)
26a
24
24a
Glucose (mg/dl)
26
28
Triglycerides (mg/dl)
28a
22
22a
Smoking (number of cigaret-tes)
30
HDL choles-terol (mg/dl)
30a
20
Age (years)
20a
34
32
36
14
BMI Weight(kg) / (height)² in m
14a
18
Systolic pressure (mm Hg)
18a
16
Diastolic pressure (mm Hg)
16a

Fig. 2

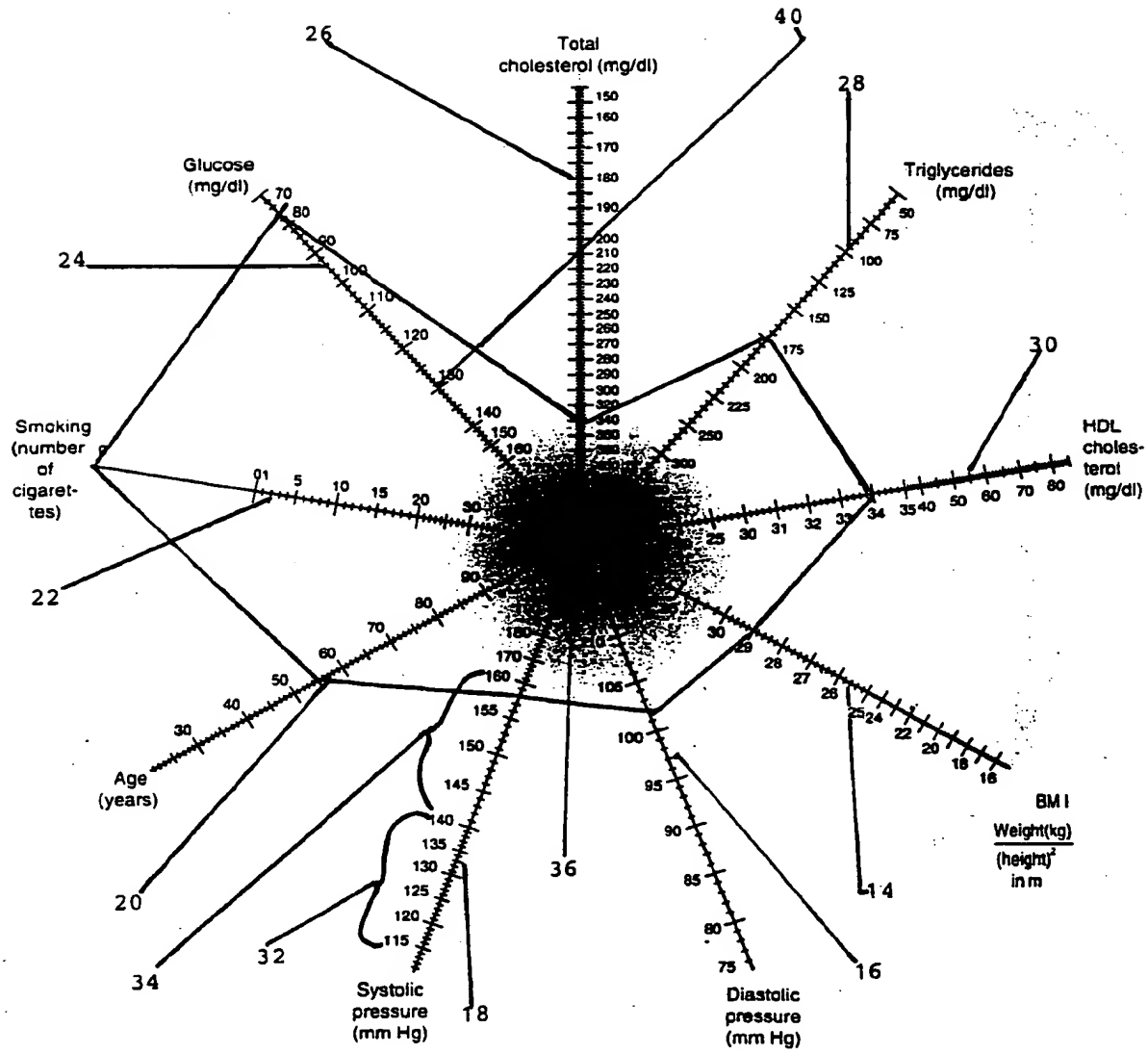
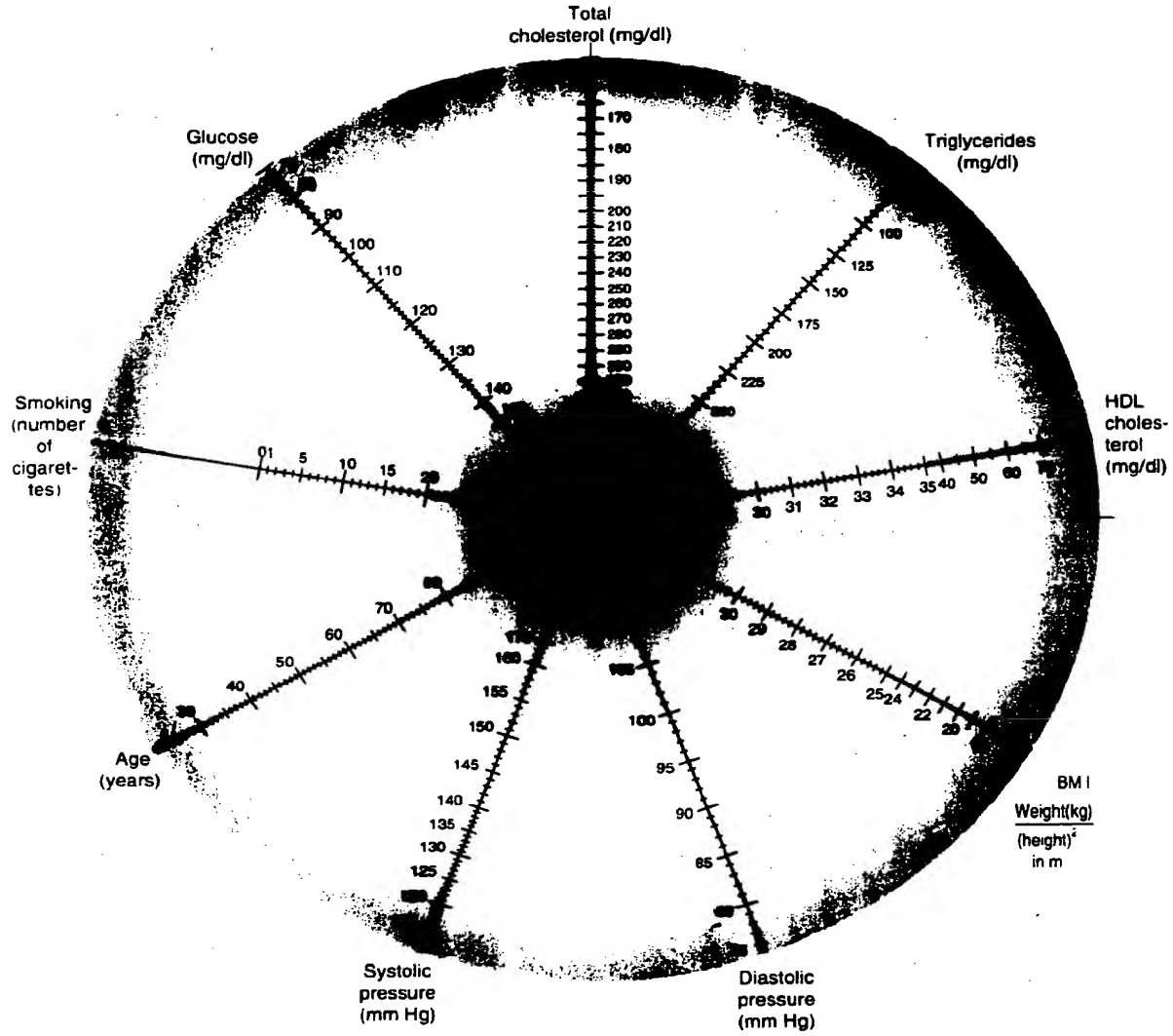

26
Total cholesterol (mg/dl)
40
28
Glucose (mg/dl)
Triglycerides (mg/dl)
24
30
Smoking (number of cigaret-tes)
HDL choles-terol (mg/dl)
22
Age (years)
20
34
32
Systolic pressure (mm Hg)
18
36
Diastolic pressure (mm Hg)
16
14
BMI
Weight(kg)
(height)²
in m

Fig. 3


Total cholesterol (mg/dl)
Triglycerides (mg/dl)
HDL cholesterol (mg/dl)
BMI
Weight(kg)
(height)²
in m
Diastolic pressure (mm Hg)
Systolic pressure (mm Hg)
Age (years)
Smoking (number of cigarettes)
Glucose (mg/dl)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 92 11 6918

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	US-A-4 930 519 (C.A.ANDERSON ET AL) * column 1, line 45 - column 2, line 50 * * column 3, line 61 - column 6, line 32; figures 1-4 *	1-4, 6-11, 13-17, 21-25	A61B5/0205
Y,D	EUROPEAN HEART JOURNAL vol. 12, December 1991, LONDON, GB, pages 291 - 297 ERICA RESEARCH GROUP, 'Prediction of coronary heart disease in Europe The 2nd report of the WHO-ERICA Project' * page 292, left column, line 11 - page 294, right column, line 9 *	1-4, 6-11, 13-17, 21-25	
A	DE-A-2 348 582 (GENERAL ELECTRIC CO.) * page 5, line 19 - page 13, line 1; figures 1,3-5 *	1-27	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	10 MAY 1993	WEIHS J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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